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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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WARREN

P.

DIVER1240-5

HM12/0706

LISA A HALE PHIL

GRAY CARY WARE & FREIDENRICH LLP

4365 EXECUTIVE DRIVE

SUITE1600

SAN DIEGO CA 92121-2189

EXAMINER

SLOBODYANSKY, E

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

07/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.
09/389,537

Applicant(s)
Warren et al.

Examiner
Elizabeth Slobodyansky

Group Art Unit
1652



☒ Responsive to communication(s) filed on May 1, 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-14 and 17-24 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 12-14, and 17-24 is/are rejected.

☒ Claim(s) 4-11 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 12

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The amendment filed May 1, 2001 amending the specification to delete references to ATCC Deposit Nos., canceling claim 1 and amending claims 1 and 17 has been entered.

Claims 1-14 and 17-24 are pending.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-3, 13, 14 and 17-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The examiner notes that claims 1-3, 13 and 14 are not drawn to an aspartate aminotransferase having an amino acid sequence that is 70% identical to SEQ ID NO: 29, for example, but to any aminotransferase.

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Claims 1-3 are drawn to a polynucleotide encoding an aminotransferase having an amino acid sequence which is 70% identical to SEQ ID NOs: 25-32. Claims 17-24 are drawn to a probe comprising 10-50 nucleotides that is 70% identical to a DNA encoding SEQ ID NOs: 25-32.

The term "aminotransferase" encompasses diverse class of enzymes having different substrate and stereo specificity. While enzymes having amino acid sequences of SEQ ID NOs: 25-32 are specific transaminases or aminotransferases, it is unknown what specific transaminase or aminotransferase will have an amino acid sequence that is 70% identical to said sequences.

The putative activity of enzymes having the amino acid sequences of SEQ ID NOs:25-32 is based on the homology with other enzymes (pages 4-5; pages 7-8, Table 1). This homology is on average about 40%. An enzyme with 70% identity will be about 30% homologous to the known sequence. The enzymes to which SEQ ID NOs: 25-32 are homologous have different substrate and stereo specificity. The correlation between the structure and function is not disclosed in the specification nor is known in the art. Therefore, it is unpredictable what will be the specific transaminase or aminotransferase function of a protein having an amino acid sequence that is 70% homologous to the claimed sequences. The specification does not disclose identifying characteristics which would allow to distinguish an aminotransferase of a specific substrate and stereo specificity from another aminotransferase.

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With regard to claims 17-24, the specification teaches the putative function of enzymes of SEQ ID NOs: 25-32, said enzymes have different specificity for the amino group donor and acceptor (pages 4-5; pages 7-8, Table 1, for example, SEQ ID NOs: 27 and 30-32). The specification does not disclose identifying characteristics which would allow to distinguish a transaminase or aminotransferase of a specific substrate and stereo specificity from another transaminase or aminotransferase. It is unpredictable what function would be encoded by a DNA that hybridizes under mild conditions recited in claim 17 with a probe of 10-50 nucleotides that is only 70% complementary to a DNA encoding SEQ ID NOs: 25-32. Said probes would hybridize to DNAs encoding many functionally and structurally unrelated proteins. While the claims impart a structural limitation (70, 90 or 95%), there is no functional limitation.

Thus, a DNA encoding an aminotransferase of unknown specificity having an amino acid sequence which is 70% identical to SEQ ID NOs 25-32 and a probe of 10-50 nucleotides that has 70, 90 or 95% complementarity to a DNA encoding SEQ ID NOs: 25-32 lack sufficient written description.

Claims 1-3, 13, 14 and 17-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide encoding an aminotransferase having an amino acid sequence as set forth in SEQ ID NOs: 25-32 and a fragments thereof of 10-50 nucleotides, does not reasonably provide enablement

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for a polynucleotide encoding an aminotransferase of unspecified specificity having an amino acid sequence 70% identical to SEQ ID NOs: 25-32 and a probe of 10-50 nucleotides that are 70% complementary to a polynucleotide encoding SEQ ID NOs: 25-32. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As noted above, the claims are not drawn to an aspartate aminotransferase having an amino acid sequence that is 70% identical to SEQ ID NO: 29, for example, but to any aminotransferase.

Factors to be in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

Despite knowledge in the art to produce mutations in proteins and the isolation of DNA molecules, the specification fails to provide guidance as to where, and what type of (i.e., what amino acid to substitute into, add to and/or delete from the known sequence), changes in amino acid residues will result in a specific aminotransferase

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activity. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

The state of the art does not allow the predictability of the properties based on the structure. The amino acid sequence of a protein determines its structural and functional properties and knowledge of which residues can be altered or removed, so that they retain 70% identity, and result in an unspecified aminotransferase activity is well outside the realm of routine experimentation. Since the state of the art does not allow the predictability of the properties based on the structure, it is unpredictable what will be the function, substrate and stereo specificity of an aminotransferase with the amino acid sequence 70% identical to SEQ ID NOs:25-32.

Furthermore, the specification does not teach what is the function of all polypeptides encoded by a polynucleotide that hybridizes with a 10-50 nucleotide probe that is 70, 90 or 95% complementary to the target DNA. As discussed above, it is unpredictable at the present state of the art. Without knowing the function, one of ordinary skill in the art would not know how to use a polypeptide.

Therefore, one skilled in the art would require guidance as to how to make a polynucleotide encoding an aminotransferase of an unspecified specificity having an amino acid sequence that is 70% identical to SEQ ID NOs:25-32 and how to use a probe that is 70, 90 or 95% complementary to an unspecified area of a DNA encoding SEQ ID NOs:25-32 that hybridizes to a DNA encoding a polypeptide of unknown

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function in a manner reasonably correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 12 and 17-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to a DNA encoding an enzyme with aminotransferase activity. However, clauses a) and b) recite SEQ ID NOS: 25-32 that are amino acid sequences while clause c) recites nucleic acid sequences. Further, regarding clause b), SEQ ID NOS: 25-32 contain neither "T" nor "U". Regarding clause c), a complementary strand does not encode the protein in question.

The scope of the term "an enzyme with aminotransferase activity" is unascertainable because it is unclear what are enzymes other than aminotransferases that are included in the scope of the claim.

Claim 12 recites "the sequences as set forth in SEQ ID NOS: 17-24". It should recite "in any one of SEQ ID NOS: 17-24", for example.

Claim 17 is drawn to a probe of "about 10 to 50 nucleotides". It is unclear whether 9 or 11 amino acids are included in the scope, for example. Such particular

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use of "about" renders the metes and bounds of the claim unascertainable. It further recites "an area of nucleotides that is at least 70% complementary". It is unclear either said area is the entire probe or a fragment thereof.

Claims 18-24 are rejected as dependent from claim 17. Further, in claim 22 there is no antecedent basis for "bases".

Double Patenting

Claims 1-3, 13 and 14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/412,184. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: a polynucleotide having at least 70% identity to a nucleic acid encoding SEQ ID NOs:25-32.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This double patenting rejection is reiterated from the Office action mailed January 30, 2001 (page 8, last paragraph).

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Allowable Subject Matter

Claims 4-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

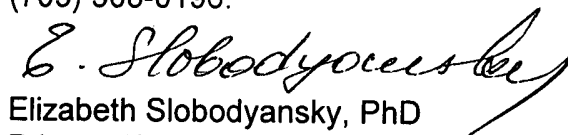
Terminal Disclaimer

The terminal disclaimer filed on May 1, 2001 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patents 5,814,473 and 6,013,509 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.


Elizabeth Slobodyansky, PhD
Primary Examiner

July 2, 2001